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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ALSTRUM ACEVEDO, JAMES HENRY	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/759,280	PEART ET AL.	
	Examiner	Art Unit	
	James H. Alstrum-Acevedo	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *23-56* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/20/04, 7/21/05 &*. 7/29/2005
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 23-56 are pending.

Specification

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f). **Specifically, the specification incorporates WO 01/03690 by reference on page 18 of the disclosure.**

The disclosure is objected to because of the following informalities: the Latin phrase "*ad libitum*" in the last sentence of the third paragraph on page 20 should be italicized, as it is standard practice to italicize words from non-English languages.

Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 24, 30-36, and 41-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 30-36, 41-42, 49, and 56 use the term "sufficient," which is vague and indefinite. A person of ordinary skill in the art would not be able to ascertain what Applicant intended by sufficient, without undue experimentation. The dosage appropriate to relieve symptoms for one person is not necessarily the appropriate dosage to relieve the same symptoms in another person.

Claims 23 and 37 recite the indefinite limitation "...not more than 15% of a pharmaceutically acceptable solvent..." This limitation is indefinite, because it is unclear whether the value of 15% is intended as a weight percent or a volume percent.

The term "pure form" in claims 24, 44, and 51 is a relative term, which renders the claim indefinite. The term "pure form" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is well known in the art that it is possible to reduce levels of impurities in a given compound, however one can never absolutely remove all impurities (See, for example, *Purification of Laboratory Chemicals, 4th edn.* W.L. F. Amarego and D.D. Perrin, Eds.; Elsevier, 1996, p 1). In other words, 100% impurity is unachievable. The term "pharmaceutically pure form" is indefinite, because it is unclear what level of purity is pharmaceutically acceptable for the instant active agent (e.g. 80%, 90%, 99%, 99.999%, 100%, etc.).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 23, 24, 26-28, 30-35, 37-44, 46-48, 50, 51, and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804592) in view of McNally et al. (U.S. Patent No. 5,653,961).

Volicer teaches methods for improving disturbed behavior and negative mood in animals comprising administering an effective amount of **dronabinol (tetrahydrocannabinol)** (col. 1, lines 17-19 and col. 2, lines 30-31). Dronabinol may be administered either alone or in combination with pharmaceutically effective **carriers, additives, or with other medications** (col. 2, lines 39-42 and 52-54). Dosages of dronabinol may vary widely from about 0.01 to 35 mg/kg of body weight administered one to five times per day (col. 2, lines 47-51). The dose used will be determined by the strength of a particular composition employed and the condition of the person, as well as the body weight of the person to be treated (col. 5, lines 33-35).

Volicer teaches that **pharmaceutically acceptable carriers** are well known to skilled artisans and that the carrier choice will be determined by the particular composition and the method of administration (col. 4, lines 29-33).

Volicer teaches that acceptable dosage forms include, inhalation (col. 4, line 40) and that **aerosol formulations of dronabinol** administered via inhalation can be placed into pressurized **acceptable propellants, including dichlorodifluoromethane, propane, nitrogen, and the like** (col. 5, lines 3-8).

Mechoulam et al. teach tetrahydrocannabinol-7-oic acids and their derivatives (including pharmaceutically acceptable salts) and pharmaceutical compositions containing these compounds, which possess **analgesic, anti-inflammatory, anti-emetic** properties and can also be used to alleviate certain chronic degenerative diseases, including **Parkinsonism and multiple sclerosis** (abstract; col. 4, lines 58-67; and col. 5, lines 1-10).

Mechoulam teaches that the compositions may be administered intra-nasally as an aerosol (i.e. inhaled) and via similar routes of administration (col. 5, lines 33-35). The dosage

for these tetrahydrocannabinol derivatives will range from 1.0 mg to about 20 mg/kg body weight. However, it is evident to the man skilled in the art that dosages would be determined by the attending physician, according to the disease to be treated, method of administration, patient's age, weight, counterindications and the like (col. 5, lines 40-45).

Mechoulam and Volicer lack an explicit teaching of aerosol formulations comprising hydrofluoroalkanes.

McNally teaches butixocort **aerosol formulations** in **hydrofluoroalkane propellant**, including 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3,3-heptafluoropropane, and a mixture thereof (title and abstract). McNally also teaches the desirability of using hydrofluoroalkanes in lieu of chlorofluorocarbon propellants, because at the time of the instant invention, chlorofluorocarbons were being phased out in favor of propellants, such as hydrofluorocarbons, which were known to be less harmful to the ozone layer (col. 1, lines 25-31).

McNally teaches that well-known methods of solubilizing include the use of cosolvents for the drug (e.g. alcohols, including ethanol), wherein **ethanol** is the preferred cosolvent (col. 2, lines 51-58 and 61-62). Ethanol used in McNally's invention constitutes **about 3 to about 30 percent by weight of the total weight of the formulation** (col. 3, lines 1-2).

McNally teaches in Examples 1 and 2 that the aerosol formulations of his invention have droplet sizes with a respirable fraction ranging from 45-69%, wherein the term "respirable fraction" is the percent by weight of particles having an aerodynamic particle size less than 4.7 microns (col. 4, lines 29-31).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Mechoulam or Volicer with McNally, because all

inventors teach pharmaceutical aerosol formulations comprising propellant. A skilled artisan at the time of the instant application would have been further motivated to combine the teachings of McNally with those of Mechoulam or Volicer, because at the time of the instant invention chlorofluorocarbons were being phased out in favor of alternatives (e.g. hydrofluoroalkanes), which were less prone to damage the ozone layer. A person of ordinary skill in the art at the time of the instant invention would have had a reasonable expectation of successfully combining the teachings of the prior art, because Volicer and Mechoulam teach aerosol formulations of tetrahydrocannabinol for administration by inhalation and the use of cosolvents (e.g. ethanol) in aerosol formulations was well known (McNally). Furthermore, a skilled artisan would have had a reasonable expectation of success, because the use of THC to treat nausea, vomiting, reduce pain, relieve muscle spasticity, migraines, and movement disorders, is taught by the prior art relied upon, which existed at the time of the instant invention.

Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804592) in view of McNally et al. (U.S. Patent No. 5,653,961) as applied to claims 23, 24, 26-28, 30-35, 37-44, 46-48, 50, 51, and 53-55 above, and further in view of *Workshop on the Medical Utility of Marijuana* (from the IDS: page 4, 2nd paragraph in the section entitled "Appetite Stimulation/Cachexia." National Institutes of Health, August 1997).

The teachings of Mechoulam or Volicer and McNally have been set forth above.

Mechoulam or Volicer and McNally lack the teaching of administering THC to treat cachexia.

The *Workshop on the Medical Utility of Marijuana* teaches that tetrahydrocannabinol (THC), the main active in marijuana, may be used to increase appetite (i.e. treat cachexia) and produce weight gain in AIDS and cancer patients (page 4, 2nd paragraph in the section entitled "Appetite Stimulation/Cachexia" in *Workshop on the Medical Utility of Marijuana*, National Institutes of Health, August 1997).

It would have been obvious to a person of ordinary skill in the art to use the THC compositions resulting from the teachings of Mechoulam or Volicer and McNally in view of the *Workshop on the Medical Utility of Marijuana* to treat cachexia, because marijuana was known to have been used to increase the appetite of AIDS and cancer patients suffering from cachexia and THC is the primary active agent in marijuana. Therefore, a skilled artisan would have had a reasonable expectation of successfully treating cachexia by administering an aerosol composition comprising THC.

Claims 25, 45, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804592) in view of McNally et al. (U.S. Patent No. 5,653,961) as applied to claims 23, 24, 26-28, 30-35, 37-44, 46-48, 50, 51, and 53-55 above, and further in view of Pars et al. (U.S. Patent No. 3,728,360).

The teachings of Mechoulam or Volicer and McNally have been set forth above.

Mechoulam or Volicer and McNally lack the teaching of compositions comprising pharmaceutically acceptable salts of tetrahydrocannabinol.

Pars et al. in teach the use **pharmaceutically acceptable salts of THC ester derivatives** (abstract; col. 5, lines 9-20 and 27-35; col. 6, lines 21-45).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Mechoulam or Volicer and McNally in view of Pars et al. and use pharmaceutically acceptable salts of THC, because the THC derivatives taught by Pars are obvious over tetrahydrocannabinol taught by Volicer and the THC-derivatives taught by Mechoulam. Therefore, a skilled artisan would have had a reasonable expectation of success upon the use of pharmaceutically acceptable salts of THC-derivative esters, such as those taught by Pars.

Claims 29, 49, and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mechoulam et al. (U.S. Patent No. 5,804,592) or Volicer (U.S. Patent No. 5,804592) in view of McNally et al. (U.S. Patent No. 5,653,961) as applied to claims 23, 24, 26-28, 30-35, 37-44, 46-48, 50, 51, and 53-55 above, and further in view of Ohlsson, A. *et al.* (*Clin. Pharmacol. Ther. 28*, 409-416).

The teachings of Mechoulam or Volicer and McNally have been set forth above.

Mechoulam or Volicer and McNally lack the teaching of THC serum concentrations of 10-100 ng/ml 15 minutes after inhalation.

Ohlsson teaches that THC is readily absorbed by inhalation (e.g. via the smoking of a marijuana cigarette), resulting in serum levels as high as 118 ng/ml and remaining as high as 18 ng/ml after 30 minutes (See, Fig. 1 in Ohlsson, A. *et al. Clin. Pharmacol. Ther. 28*, 409-416).

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Mechoulam or Volicer and McNally in view of Ohlsson to expect an observation of THC serum concentrations of 10-100 ng/ml 15 minutes after inhalation, because Ohlsson's teaches time-dependent serum concentrations of THC in subjects who have smoked marijuana, which is known to contain THC as a primary active agent. It would have been apparent to a person of ordinary skill in the art at the time of the instant invention that inhalation of a THC aerosol would have yielded blood serum levels of THC in a patient of 10-100 ng/ml fifteen minutes after inhalation, per the teachings of Ohlsson. A skilled artisan would have had a reasonable expectation of successfully observing serum concentration levels of THC of 10-100 ng/ml in a patient 15 minutes after inhalation based upon the teachings of the prior art. Furthermore, the amount of THC required to achieve serum concentration levels of 10-100 ng/mL 15 minutes after inhalation is a property of the composition that a skilled artisan is capable of controlling by varying the amount of THC and other components, because it is recognized in the art that dosages are determined, in part, according to the disease to be treated, method of administration, patient's age, weight, counterindications and the like (Mechoulam). It is also well known in the art that THC is readily absorbed by inhalation (e.g. via the smoking of a marijuana cigarette), resulting in serum levels as high as 118 ng/ml and remaining as high as 18 ng/ml after 30 minutes.

Claims 43-48 and 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pars et al. (U.S. Patent No. 3,728,360) in view of McNally et al. (U.S. Patent No. 5,653,961).

The teachings of Pars have been set forth above, but are repeated here, along with additional relevant teachings, for Applicant's convenience.

Pars et al. in teach the use **pharmaceutically acceptable salts of THC ester derivatives** that possess biological activity and are useful as therapeutic agents (abstract; col. 5, lines 9-20 and 27-35; col. 6, lines 21-45).

Pars et al. teach that the tangible embodiments of this composition aspect of the invention possess the inherent use characteristics of having biological activity as determined by standard pharmacological test procedures for potential therapeutic drugs. The compounds of this invention are amino esters, and some of their acid addition salts are water-soluble. These esters offer the possibility of being hydrolyzed *in vivo* **to form the corresponding phenolic compound** (i.e. THC). The rate of such hydrolysis may be regulated by the nature of the ester chain (col. 1, lines16-26).

Pars et al. teach that the compounds of formula I-V have been shown to possess **central nervous system activity**, indicative of these compounds' usefulness as **psychotherapeutic agents** (col. 6, lines 60-67 and col. 7, lines 1-12).

Pars et al. teach that the compounds of their invention or a salt form thereof may be dissolved in water, saline, **aqueous alcohol**, glycol, oil solutions, or oil-water emulsions and may be administered orally or via intramuscular injection (col. 7, lines 14-28).

Pars et al. lack a teaching of aerosol formulations comprising a hydrofluoroalkane.

The teachings of McNally regarding pharmaceutical aerosol formulations comprising hydrofluoroalkane propellant have been set forth above.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Pars and McNally to obtain pharmaceutical aerosol formulations, because McNally teaches pharmaceutical aerosol formulations comprising an active agent, hydrofluoroalkane propellant, and/or ethanol and Pars teaches active THC compounds and formulations comprising ethanol. A skilled artisan would have had a reasonable expectation of combining the teachings of Pars and McNally, because Pars teaches that his compounds and salts thereof are soluble in aqueous alcohol (i.e. aqueous ethanol). Therefore, a skilled artisan would have had the reasonable expectation of obtaining an aerosol formulation comprising dissolved THC, or THC-ester derivative, or salt thereof. Furthermore, a skilled artisan would expect that administration of Pars' THC-ester derivatives would result in observable THC serum concentrations, because the THC-ester derivatives are expected to hydrolyze *in vivo* to the phenolic compound (i.e. THC).

Claims 49 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pars et al. (U.S. Patent No. 3,728,360) in view of McNally et al. (U.S. Patent No. 5,653,961) as applied to claims 43-48 and 50-55 above, and further in view of Ohlsson, A. *et al.* (*Clin. Pharmacol. Ther. 28*, 409-416).

The teachings Pars and McNally have been set forth above.

Pars and McNally lack an explicit teaching regarding serum concentration of THC of 10-100 ng/ml.

The teachings of Ohlsson have been set forth above.

It would have been obvious to a person of ordinary skill in the art at the time of the instant invention to combine the teachings of Mechoulam or Volicer and McNally in view of

Ohlsson to expect an observation of THC serum concentrations of 10-100 ng/ml 15 minutes after inhalation, because Ohlsson's teaches time-dependent serum concentrations of THC in subjects who have smoked marijuana, which is known to contain THC as a primary active agent. It would have been apparent to a person of ordinary skill in the art at the time of the instant invention that inhalation of a THC aerosol would have yielded blood serum levels of THC in a patient of 10-100 ng/ml fifteen minutes after inhalation, per the teachings of Ohlsson. A skilled artisan would have had a reasonable expectation of successfully observing serum concentration levels of THC of 10-100 ng/ml in a patient 15 minutes after inhalation based upon the teachings of the prior art. Furthermore, the amount of THC required to achieve serum concentration levels of 10-100 ng/mL 15 minutes after inhalation is a property of the composition that a skilled artisan is capable of controlling by varying the amount of THC and other components. It is also known in the art that THC is readily absorbed by inhalation (e.g. via the smoking of a marijuana cigarette), resulting in serum levels as high as 118 ng/ml and remaining as high as 18 ng/ml after 30 minutes per the teachings of Ohlsson.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24, 26-29, 43, 44, 46, 48, 49, 50, and 52-56 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,509,005 (USPN '005). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope and/or the dependent claims have the similar limitations. The dependent method claims of the instant application cited above have been included in this rejection, because they further limit the composition utilized in the method and are therefore obvious over the claims of USPN '005. More specifically, the claims of the instant invention are drawn to compositions comprising tetrahydrocannabinol, whereas those of USPN '005 are drawn to compositions consisting essentially of Δ^9-tetrahydrocannabinol. The term "tetrahydrocannabinol" of the instant invention is broader, encompasses the specific isomer in the claims of USPN '005, and is therefore obvious over USPN '005. The compositions of the instant application also comprised of a hydrofluoroalkane, whereas the compositions of USPN '005 consist essentially of specific hydrofluoroalkanes: 1,1,1,2,3,3,3-heptafluoropropane (HFA 227) and/or 1,1,1,2-tetrafluoroethane (HFA 134a). The term hydrofluoroalkane encompasses the two specific hydrofluoroalkane molecules in the claims of USPN '005 and for this reason

"hydrofluoroalkane" is obvious over the two specific hydrofluoroalkane molecules in the aforementioned claims of USPN '005.

Claims 23-27 and 29-36 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, and 4-16 of U.S. Patent No. 6,713,048 (USPN '048). Although the conflicting claims are not identical, they are not patentably distinct from each other because they are overlapping in scope and/or the dependent claims have the similar limitations. More specifically, the claims of the instant invention are drawn to methods of administering pharmaceutical aerosol compositions comprising tetrahydrocannabinol, whereas those of USPN '048 are drawn to compositions consisting essentially of Δ^9-tetrahydrocannabinol. The term "tetrahydrocannabinol" of the instant invention is broader, encompasses the specific isomer in the claims of USPN '005, and is therefore obvious over USPN '005.

Conclusion

The specification is objected. Claims 23-56 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni (Paddy) Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

James H. Alstrum-Acevedo, Ph.D., Examiner

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER